

Remarks

This is in response to the Final Office Action mailed on December 1, 2006. This Amendment is filed on the two-month response date, therefore an advisory action is requested. Claims 1-8 remain pending. Claims 9 and 10 are added, with support found in the original claims and throughout the specification. No new matter is added. Reconsideration and allowance are requested in view of the following remarks.

With this Response, claims 1, 2, 3, and 6 are amended to remove the term “complex” and specify tri- and tetra- metal salts of hydroxycitric acid. The claims remain directed to compositions and processes related to a tri- or tetra- metal salt of hydroxycitric acid wherein the salt comprises at least three different metals selected from zinc, magnesium, sodium, potassium, and calcium. New claims 9 and 10 have been added directed to a tri- or tetra- metal salt of hydroxycitric acid wherein the salt comprises at least three different metals selected from zinc, magnesium, sodium, potassium, and calcium.

To further assist in understanding the claimed a tri- or tetra- metal salt of hydroxycitric acid, a declaration by one of the inventors presenting molecular representations of various embodiments of the claimed tri- or tetra- metal salt of hydroxycitric acid is provided.

Interview

An in-person interview was held with Examiner OH on November 29, 2006. The subject matter of claim 1 was discussed and clarification of “complex” recommended. A copy of the interview summary is provided with this paper.

35 U.S.C. § 102

Claims 1, and 4-5 are rejected as allegedly anticipated by Clouatre et al., U.S. 6,447,807. Applicants respectfully traverse.

Clouatre is asserted to teach a method of making potassium and sodium salts of hydroxycitric acid and mixtures thereof which are encased in order to be workable, non-

hygroscopic and non-reactive in acidic media. Applicants disagree that the salt compositions of Clouatre anticipate the claimed HCA compositions.

Under 35 U.S.C. §102, “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Independent claim 1, as amended, is directed to composition comprising a **tri- or tetra-metal salt** of hydroxycitric acid (HCA) wherein the salt comprises at least three different metals selected from zinc, magnesium, sodium, potassium, and calcium.

In contrast, the methods Clouatre describe encased potassium salts of hydroxycitric acid or encased sodium salts of hydroxycitric acid. In particular, Clouatre teaches a method for making a workable, non-hygroscopic and non-reactive form of KHCA for controlled delivery. It is well known that potassium and sodium salts are highly hygroscopic and very difficult to handle. See Clouatre, col. 3, lines 19-21. To overcome this difficulty Clouatre provides an encapsulation method (see col 5, lines 34-67) wherein a physical mixture of additives mixed with a simple salt of hydroxycitric acid are spray dried prior to granule or tablet formation. Clouatre et al also applied the above encapsulation method to other non-preferred simple salts of HCA (see col. 9 lines 1-5) such as calcium hydroxycitrate, or magnesium hydroxycitrate, and various mixtures of simple salts.

Clouatre does not disclose tri- or tetra- metal salts of HCA. The disclosed potassium or sodium salts are “simple salts” wherein an HCA forms ionic bonds to a **single** type of metal. In contrast, the claimed tri- or tetra- metal metal salts of HCA include at least one HCA coordinated with three or four different metals. Three of those different metals, Mg, Ca and Zn, are bivalent. Consequently, tri- or tetra-metal salts of HCA can include two or more individual HCA molecules. Representative examples illustrating structure of a three- and a four-metal salt of HCA is shown in a Declaration of inventor Philip Samuel, provided with this Response.

The present invention provides salts of HCA with multiple different metals; not a physical mixture of different individual single metal salts as is described by Clouatre. Therefore, a single metal salt or a mixture of single metal salts is distinctly different from the claimed tri- or tetra- metal salt of HCA.

In addition, Clouatre does not disclose forming salts of HCA wherein an HCA is coordinated with at least **three different metals** selected from zinc, magnesium, sodium, potassium, and calcium. Therefore, Clouatre fails to meet all the limitations of independent claim 1 and consequently also does not meet all the limitations of dependent claims 4-5 for at least those reasons provided above. Consequently, Clouatre cannot anticipate claims 1, 4 and 5.

35 U.S.C. § 103

Claims 1-8 are rejected as allegedly obvious over Clouatre in view of Moffett, U.S. 5,656,314. Applicants respectfully traverse.

To support a rejection under 35 U.S.C. section 103, the collective teachings of the prior art must have suggested to one of ordinary skill in the art that, at the time the invention was made, applicant's claimed invention would have been obvious. A prima facie case of obviousness requires that **1)** the references when combined must teach or suggest all of the claim limitations; **2)** a suggestion or motivation to modify the references or combine the reference teachings must be present; and **3)** the references when combined must provide a reasonable expectation of success. Applicants believe that all of these requirements have not been met.

Clouatre is asserted to teach a method of making potassium and sodium salts of hydroxycitric acid and mixtures thereof which are encased in order to be workable, non-hygroscopic and non-reactive in acidic media. Moffett is asserted to teach a method of removing salts from Garcinia water extract, including isolation of hydroxycitric acid as calcium hydroxycitrate. Clouatre's methods for encapsulating simple salt compositions in view of Moffett's isolation methods is alleged to allow one to produce various mixtures of known salts in liquid acidic form. Applicants respectfully disagree that the combination of Clouatre and Moffett renders the claimed invention obvious.

Independent claim 1 and dependent claims 2-5 are directed to composition comprising a tri- or tetra- metal salt of hydroxycitric acid (HCA) wherein the salt comprises at least three different metals selected from zinc, magnesium, sodium, potassium, and calcium. Independent claim 6 and dependent claims 7-8 are directed to a process for preparing a tri- or tetra- metal salt of hydroxycitric acid (HCA) by reacting liquid hydroxycitric acid with a mixture of at least three different metal bases.

1. Clouatre and Moffett, when combined, do not teach all of the elements of the claimed invention.

Clouatre does not teach or suggest tri- or tetra- metal salts of HCA including at least three different metals selected from zinc, magnesium, sodium, potassium, and calcium. Moffett does not correct the deficiencies of Clouatre. Moffett does not teach or suggest tri- or tetra- metal salts of HCA including at least three different metals selected from zinc, magnesium, sodium, potassium, and calcium. In addition, neither Clouatre or Moffett, alone or in combination, suggest a mixture of three or more metal bases selected from zinc, magnesium, sodium, potassium, and calcium in a process for preparing a hydroxycitric acid salt. Consequently, Clouatre even when combined with Moffett does not teach all the limitations of independent claims 1 and 6.

2. No motivation to combine Clouatre with Moffitt or modify the references has been shown.

Clouatre teaches encased forms of KHCA, while Moffitt teaches Moffett et al (US Patent 5,536,516) describes a method of producing HCA concentrate in LIQUID form which contains mostly HCA lactone, which is biologically less active than HCA.

There is no suggestion to combine the Clouatre's solid forms of KHCA, which are encased to protect against humidity, with Moffitt's liquid form which not suitable for making tablets because of it high acidity and stability problems. The disadvantages of Moffitt's liquid HCA for various applications are clearly presented in a later patent with a common inventor (Balasubramanyan). See U.S. 6,160,172, col 2, lines 6-21, reproduced below.

In our earlier patents (Indian patent No. 178298 & U.S. Pat. Nos. 5536516, 5656314) which describes preparation of a concentrate of (-) hydroxycitric acid and its lactone in liquid form, comprising of several steps like water extraction of Garcinia rind containing (-) hydroxycitric acid and its concentration, acetone refinement of this concentrated water extract, evaporation of acetone, loading thus obtained refined extract on ion-exchange columns containing an anion exchange resin followed by a cation exchange resin, and finally evaporation of the free acid liberated from the ion-exchange process to said concentration. This liquid form of (-) hydroxycitric acid has problems of stability and half-life.

In addition, its highly acidic nature poses problems in formulating into beverage and various other food products without affecting their flavor and properties.

In addition, Clouatre teaches encapsulation to protect a simple potassium salt of HCA from degradation and conversion to the lactone. In contrast Moffitt converts at least a portion of its liquid form of HCA into the lactone form.

Significant differences are present between the solid HCA salts of Clouatre and liquid HCA lactone forms of Moffitt. Neither reference presents motivation for combining their teachings and no suggestion of how or why to modify the references to render them compatible. Hence, there is no motivation to combine.

3. Clouatre and Moffitt, even if combined, do not provide a reasonable expectation of success.

The simple salts of Clouatre require encapsulation in inert materials to protect them from environmental moisture and acid (to prevent lactonization). In contrast, Moffitt is directed to an acidic liquid form predominately of HCA lactone. Clouatre and Moffitt, even if combined, do not teach or suggest an HCA salt that is stable to environmental moisture without decomposing and acid-stable without lactonization. Hence, there is not a reasonable expectation of one successfully producing the stable, metal HCA salt as claimed based solely on the teachings of Clouatre and Moffitt.

The claimed HCA salts and related process are entirely different from those described by Clouatre and Moffitt:

- The invention provides HCA 3 or 4 metal salt and process for producing HCA 3 or 4 metal salt which is stable and does not require any stabilization in formulation to prevent lactonization.
- The claimed composition is a non-hygroscopic powder and consequently does not require encapsulation or other means to protect from environmental moisture.
- In addition, the spray drying temperatures of Clouatre of greater than 200°C, while suitable for encased materials, are detrimental to HCA compositions where such additives are not required.

Conclusion

A prima facie case of obvious has not been presented. Clouatre and Moffitt do not teach all the limitations of the claims. There is no motivation to combine or modify the references and no likelihood of success as neither Clouatre nor Moffitt have solved the problem of water and acid instability of HCA salts. Therefore, independent claims 1 and 6 are patentable in view of Clouatre and Moffitt. Since dependent claims include the same limitations as the independent claims from which they depend the same reasoning applies.

In addition, the claimed HCA salts present a novel solution solving both the problems of moisture and acid instability.

The remarks set forth above provide certain arguments in support of the patentability of the pending claims. There may be other reasons that the pending claims are patentably distinct

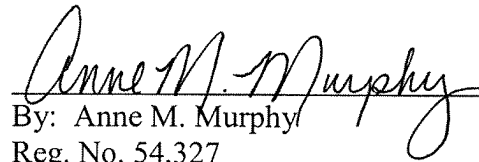
over the cited references, and the right to raise any such other reasons or arguments in the future is expressly reserved.

Favorable reconsideration in the form of a Notice of Allowance is requested. Please contact the undersigned attorney with any questions regarding this application.

Respectfully submitted,

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